

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF PENNSYLVANIA

ROBERT SHAH,

Plaintiff,

- v -

WALTER RINEHART, et al.,

Defendants.

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Civil Action No. 04-259 (Erie)

DECLARATION OF JOYCE HORIKAWA

I, Joyce Horikawa, make the following declaration under penalty of perjury:

1. I am an Attorney Advisor employed by the United States Department of Justice, Federal Bureau of Prisons, Northeast Regional Office, Philadelphia, Pennsylvania. I have been employed in this capacity since approximately April 8, 2001. As an Attorney Advisor, I have access to most documents maintained in the ordinary course of business at the Federal Bureau of Prisons, Northeast Regional Office, including records maintained in the Bureau of Prisons nationwide computer data base.

2. I am familiar with Bureau of Prisons policies and procedures pertaining to the processing of administrative tort claims asserted under the Federal Tort Claims Act, 28 U.S.C. §§ 2671 et seq., (hereinafter FTCA), and submitted to the Bureau of Prisons pursuant to 28 C.F.R. §§ 543.30-.32.

3. The Bureau of Prisons' regulations applicable to administrative claims asserted under the FTCA require claims to be submitted first to the Regional Office in the region where the basis for the claim occurred. 28 C.F.R. § 543.31(c). The Federal Correctional Institution (FCI), McKean, Pennsylvania, is a facility located within the territorial boundaries of the Northeast Region of the Bureau of Prisons. 28 C.F.R. §§ 503.2(b)(5). Thus, any administrative tort claim arising out of the conditions at FCI McKean would be processed by the Bureau of Prisons Northeast Regional Counsel's Office in Philadelphia, Pennsylvania.

GOVERNMENT  
EXHIBIT  
C

4. Under the applicable regulations, the denial of a claim by either the Regional Counsel or his/her designee, or the Office of the General Counsel constitutes a final administrative action, and if a claimant is dissatisfied with the final action, he/she may file suit in an appropriate U.S. District Court as no further administrative action is available. 28 C.F.R. § 543.32(g).

5. In connection with the above-captioned civil action, I accessed the administrative tort claim filed by inmate Robert Shah, Reg. No. 01215-039, to determine if and/or when he filed and/or exhausted his administrative remedies under the FTCA for any allegation set forth in the complaint he filed in the above-captioned civil action. A search of these tort claim records reveals that on or about June 30, 2003, Plaintiff filed an administrative tort claim with the Federal Bureau of Prisons Northeast Regional Office. In a memorandum dated November 20, 2003, Plaintiff's administrative tort claim was denied. This denial memorandum was receipted by inmate Shah on November 25, 2003. The denial memorandum advised inmate Shah that if he was not satisfied with the decision, he could file a lawsuit in United States District Court within six months of the date of the memorandum. See Memorandum dated November 20, 2003, attached hereto.

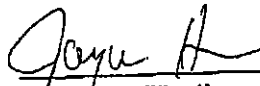
6. On or about November 7, 2005, I accessed the Pacer Civil Docket sheet for the above-captioned civil action to determine whether inmate Shah filed this lawsuit within six months of either November 20, 2003, or November 25, 2003. My review of the docket sheet for this civil action revealed that inmate Shah filed this lawsuit on September 14, 2004, which is approximately nine months after both the date and inmate Shah's receipt of the denial memorandum from the Bureau of Prisons Northeast Regional Counsel.

7. Attached hereto, please find true and correct copies of the following records that are maintained in the ordinary course of business in the Bureau of Prisons, Northeast Regional Office:

- a. Public Information Data for former inmate Robert Shah, Register Number 01215-039;
- b. Request for Administrative Remedy, Case Number 343051, and Response dated July 29, 2004;
- c. Regional Administrative Remedy Appeal, Case Number 343051-R1, and response dated September 15, 2004;
- d. Central Office Administrative Remedy Appeal, Case Number 343051-A1, and response, dated November 16, 2004; and
- e. Pierre, Joseph, M., M.D., *High-Dose Antipsychotics: Desperation or data-driven?* Current Psychiatry Online, Vol 3, No. 8; and
- f. Tort Claim Denial Memorandum, and Acknowledgment of Receipt of Denial of Tort Claim, signed by inmate Robert Shah, Reg. No. 01215-039, on November 25, 2003.

I declare the foregoing is true and correct to the best of my knowledge and belief, and is given under penalty of perjury pursuant to 28 U.S.C. § 1746.

Executed this 21<sup>st</sup> day of November, 2005.

  
\_\_\_\_\_  
Joyce M. Horikawa  
Senior Attorney Advisor  
Philadelphia, PA

## **Document 1a**

NERH4 \* PUBLIC INFORMATION \* 10-21-2005  
 PAGE 001 \* INMATE DATA \* 08:36:05  
 AS OF 10-21-2005

REGNO...: 01215-039 NAME: SHAH, ROBERT ARBEB

RESP OF: CDT / GOOD CONDUCT TIME RELEASE

PHONE...: 313-226-6186 FAX: 313-226-7327

RACE/SEX...: WHITE / MALE

DOB/AGE....: 12-12-1942 / 62

FBI NUMBER.: 577315D

ACTUAL RELEASE METH.: GCT REL

ACTUAL RELEASE DATE.: 09-16-2005

----- ADMIT/RELEASE HISTORY -----

FCL	ASSIGNMENT	DESCRIPTION	START DATE/TIME	STOP DATE/TIME
CDT	GCT REL	GOOD CONDUCT TIME REL (CCCA)	09-16-2005 0854	CURRENT
CDT	A-DES	DESIGNATED, AT ASSIGNED FACIL	05-17-2005 1230	09-16-2005 0854
0-Z	RELEASE	RELEASED FROM IN-TRANSIT FACL	05-17-2005 1230	05-17-2005 1230
0-Z	A-ADMIT	ADMITTED TO AN IN-TRANSIT FACL	05-17-2005 1147	05-17-2005 1230
CDT	TRANSFER	TRANSFER	05-17-2005 1147	05-17-2005 1147
CDT	A-DES	DESIGNATED, AT ASSIGNED FACIL	03-08-2005 0445	05-17-2005 1147
3-N	RELEASE	RELEASED FROM IN-TRANSIT FACL	03-08-2005 0445	03-08-2005 0445
3-N	A-ADMIT	ADMITTED TO AN IN-TRANSIT FACL	03-07-2005 1354	03-08-2005 0445
MCK	FURL TRANS	FURL W/UNESCORTED TRF TO A CCC	03-07-2005 1354	03-07-2005 1354
MCK	A-DES	DESIGNATED, AT ASSIGNED FACIL	08-17-2003 2034	03-07-2005 1354
MCK	LOCAL HOSP	ESC TRIP TO LOCAL HOSP W/RETN	08-12-2003 0748	08-17-2003 2034
MCK	A-DES	DESIGNATED, AT ASSIGNED FACIL	07-30-2003 1018	08-12-2003 0748
MCK	LOCAL HOSP	ESC TRIP TO LOCAL HOSP W/RETN	07-30-2003 0800	07-30-2003 1018
MCK	A-DES	DESIGNATED, AT ASSIGNED FACIL	06-23-2003 1226	07-30-2003 0800
MCK	LOCAL HOSP	ESC TRIP TO LOCAL HOSP W/RETN	06-23-2003 1010	06-23-2003 1226
MCK	A-DES	DESIGNATED, AT ASSIGNED FACIL	05-05-2003 1902	06-23-2003 1010
MCK	LOCAL HOSP	ESC TRIP TO LOCAL HOSP W/RETN	05-05-2003 1033	05-05-2003 1902
MCK	A-DES	DESIGNATED, AT ASSIGNED FACIL	03-24-2003 1126	05-05-2003 1033
MCK	LOCAL HOSP	ESC TRIP TO LOCAL HOSP W/RETN	03-24-2003 0933	03-24-2003 1126
MCK	A-DES	DESIGNATED, AT ASSIGNED FACIL	07-19-2002 0825	03-24-2003 0933
S18	RELEASE	RELEASED FROM IN-TRANSIT FACL	07-19-2002 0825	07-19-2002 0825
S18	A-ADMIT	ADMITTED TO AN IN-TRANSIT FACL	07-19-2002 0534	07-19-2002 0825
LEW	HLD REMOVE	HOLDOVER REMOVED	07-19-2002 0534	07-19-2002 0534
LEW	A-BOP HLD	HOLDOVER FOR INST TO INST TRF	07-15-2002 1712	07-19-2002 0534
A01	RELEASE	RELEASED FROM IN-TRANSIT FACL	07-15-2002 1712	07-15-2002 1712
A01	A-ADMIT	ADMITTED TO AN IN-TRANSIT FACL	07-15-2002 0924	07-15-2002 1712
CUM	TRANSFER	TRANSFER	07-15-2002 0924	07-15-2002 0924
CUM	A-DES	DESIGNATED, AT ASSIGNED FACIL	05-13-2002 1721	07-15-2002 0924
A01	RELEASE	RELEASED FROM IN-TRANSIT FACL	05-13-2002 1721	05-13-2002 1721
A01	A-ADMIT	ADMITTED TO AN IN-TRANSIT FACL	05-13-2002 1020	05-13-2002 1721
OKL	HLD REMOVE	HOLDOVER REMOVED	05-13-2002 0920	05-13-2002 0920
OKL	A-BOP HLD	HOLDOVER FOR INST TO INST TRF	05-08-2002 1635	05-13-2002 0920
A02	RELEASE	RELEASED FROM IN-TRANSIT FACL	05-08-2002 1735	05-08-2002 1735
A02	A-ADMIT	ADMITTED TO AN IN-TRANSIT FACL	05-08-2002 1401	05-08-2002 1735
RCH	TRANSFER	TRANSFER	05-08-2002 1301	05-08-2002 1301
RCH	A-DES	DESIGNATED, AT ASSIGNED FACIL	10-18-2001 1435	05-08-2002 1301

G0002

MORE PAGES TO FOLLOW . . .

NERH4 \* PUBLIC INFORMATION \* 10-21-2005  
 PAGE 002 \* INMATE DATA \* 08:36:05  
 AS OF 10-21-2005

REGNO...: 01215-039 NAME: SHAH, ROBERT ARBEB

RESP OF: CDT / GOOD CONDUCT TIME RELEASE  
 PHONE...: 313-226-6186 FAX: 313-226-7327

6-H	RELEASE	RELEASED FROM IN-TRANSIT FACIL	10-18-2001	1535	10-18-2001	1535
6-H	A-ADMIT	ADMITTED TO AN IN-TRANSIT FACIL	10-18-2001	0839	10-18-2001	1535
CUM	TRANSFER	TRANSFER	10-18-2001	0839	10-18-2001	0839
CUM	A-DES	DESIGNATED, AT ASSIGNED FACIL	08-30-2001	1456	10-18-2001	0839
CUM	LOCAL HOSP	ESC TRIP TO LOCAL HOSP W/RETN	08-30-2001	1215	08-30-2001	1456
CUM	A-DES	DESIGNATED, AT ASSIGNED FACIL	03-20-2001	0942	08-30-2001	1215
CUM	LOCAL HOSP	ESC TRIP TO LOCAL HOSP W/RETN	03-20-2001	0822	03-20-2001	0942
CUM	A-DES	DESIGNATED, AT ASSIGNED FACIL	08-28-2000	1014	03-20-2001	0822
CUM	LOCAL HOSP	ESC TRIP TO LOCAL HOSP W/RETN	08-28-2000	0826	08-28-2000	1014
CUM	A-DES	DESIGNATED, AT ASSIGNED FACIL	07-03-2000	1746	08-28-2000	0826
A01	RELEASE	RELEASED FROM IN-TRANSIT FACIL	07-03-2000	1746	07-03-2000	1746
A01	A-ADMIT	ADMITTED TO AN IN-TRANSIT FACIL	07-03-2000	0830	07-03-2000	1746
OKL	HLD REMOVE	HOLDOVER REMOVED	07-03-2000	0730	07-03-2000	0730
OKL	A-BOP HLD	HOLDOVER FOR INST TO INST TRF	06-16-2000	1730	07-03-2000	0730
A01	RELEASE	RELEASED FROM IN-TRANSIT FACIL	06-16-2000	1830	06-16-2000	1830
A01	A-ADMIT	ADMITTED TO AN IN-TRANSIT FACIL	06-16-2000	1117	06-16-2000	1830
BEC	TRANSFER	TRANSFER	06-16-2000	1117	06-16-2000	1117
BEC	A-DES	DESIGNATED, AT ASSIGNED FACIL	03-02-2000	1630	06-16-2000	1117
A01	RELEASE	RELEASED FROM IN-TRANSIT FACIL	03-02-2000	1630	03-02-2000	1630
A01	A-ADMIT	ADMITTED TO AN IN-TRANSIT FACIL	03-02-2000	1025	03-02-2000	1630
OKL	HLD REMOVE	HOLDOVER REMOVED	03-02-2000	0925	03-02-2000	0925
OKL	A-HLD	HOLDOVER, TEMPORARILY HOUSED	02-25-2000	1735	03-02-2000	0925
3-J	RELEASE	RELEASED FROM IN-TRANSIT FACIL	02-25-2000	1835	02-25-2000	1835
3-J	A-ADMIT	ADMITTED TO AN IN-TRANSIT FACIL	02-25-2000	1031	02-25-2000	1835
LOS	HLD REMOVE	HOLDOVER REMOVED	02-25-2000	0731	02-25-2000	0731
LOS	A-HLD	HOLDOVER, TEMPORARILY HOUSED	01-24-2000	1814	02-25-2000	0731
LOS	ADM CHANGE	RELEASE FOR ADMISSION CHANGE	01-24-2000	1813	01-24-2000	1814
LOS	A-PRE	PRE-SENT ADMIT, ADULT	01-21-2000	2017	01-24-2000	1813
6-A	RELEASE	RELEASED FROM IN-TRANSIT FACIL	01-21-2000	2317	01-21-2000	2317
6-A	A-ADMIT	ADMITTED TO AN IN-TRANSIT FACIL	01-20-2000	1305	01-21-2000	2317
BEC	FED WRIT	RELEASE ON FEDERAL WRIT	01-20-2000	1305	03-02-2000	1630
BEC	A-DES	DESIGNATED, AT ASSIGNED FACIL	01-13-2000	1512	01-20-2000	1305
A01	RELEASE	RELEASED FROM IN-TRANSIT FACIL	01-13-2000	1512	01-13-2000	1512
A01	A-ADMIT	ADMITTED TO AN IN-TRANSIT FACIL	01-13-2000	1116	01-13-2000	1512
BEC	FED WRIT	RELEASE ON FEDERAL WRIT	01-13-2000	1116	01-13-2000	1512
BEC	A-DES	DESIGNATED, AT ASSIGNED FACIL	01-06-2000	1447	01-13-2000	1116
A01	RELEASE	RELEASED FROM IN-TRANSIT FACIL	01-06-2000	1447	01-06-2000	1447
A01	A-ADMIT	ADMITTED TO AN IN-TRANSIT FACIL	01-06-2000	1018	01-06-2000	1447

G0002 MORE PAGES TO FOLLOW . . .

NERH4	*	PUBLIC INFORMATION	*	10-21-2005
PAGE 003	*	INMATE DATA	*	08:36:05
		AS OF 09-16-2005		

REGNO...: 01215-039 NAME: SHAH, ROBERT ARBEB

RESP OF: CDT / GOOD CONDUCT TIME RELEASE  
PHONE...: 313-226-6186 FAX: 313-226-7327  
PRE-RELEASE PREPARATION DATE: 03-17-2005

THE FOLLOWING SENTENCE DATA IS FOR THE INMATE'S PRIOR COMMITMENT.  
THE INMATE WAS SCHEDULED FOR RELEASE: 09-16-2005 VIA GCT REL

-----PRIOR JUDGMENT/WARRANT NO: 020 -----

COURT OF JURISDICTION.....: MICHIGAN, EASTERN DISTRICT  
DOCKET NUMBER.....: 88-CR-80114  
JUDGE.....: GILMORE  
DATE SENTENCED/PROBATION IMPOSED: 01-27-1989  
DATE COMMITTED.....: 03-20-1989  
HOW COMMITTED.....: US DISTRICT COURT COMMITMENT  
PROBATION IMPOSED.....: NO

	FELONY ASSESS	MISDMNR ASSESS	FINES	COSTS
NON-COMMITTED.:	\$50.00	\$00.00	\$00.00	\$00.00

RESTITUTION...: PROPERTY: NO SERVICES: NO AMOUNT: \$00.00

-----PRIOR OBLIGATION NO: 010 -----

OFFENSE CODE.....: 551  
OFF/CHG: BANK ROBBERY BY FORCE T18 USC 2113(A)

SENTENCE PROCEDURE.....: 3559 SRA SENTENCE  
SENTENCE IMPOSED/TIME TO SERVE.: 240 MONTHS  
TERM OF SUPERVISION.....: 5 YEARS  
DATE OF OFFENSE.....: 02-17-1988

G0002 MORE PAGES TO FOLLOW . . .

NERH4 \* PUBLIC INFORMATION \* 10-21-2005  
PAGE 004 \* INMATE DATA \* 08:36:05  
AS OF 09-16-2005

REGNO...: 01215-039 NAME: SHAH, ROBERT ARBEB

RESP OF: CDT / GOOD CONDUCT TIME RELEASE  
PHONE...: 313-226-6186 FAX: 313-226-7327

-----PRIOR COMPUTATION NO: 020 -----

COMPUTATION 020 WAS LAST UPDATED ON 05-31-2005 AT CDT AUTOMATICALLY

THE FOLLOWING JUDGMENTS, WARRANTS AND OBLIGATIONS ARE INCLUDED IN  
PRIOR COMPUTATION 020: 020 010

DATE COMPUTATION BEGAN.....: 01-27-1989  
TOTAL TERM IN EFFECT.....: 240 MONTHS  
TOTAL TERM IN EFFECT CONVERTED...: 20 YEARS  
EARLIEST DATE OF OFFENSE.....: 02-17-1988

JAIL CREDIT.....: FROM DATE THRU DATE  
03-04-1988 01-26-1989

TOTAL PRIOR CREDIT TIME.....: 329  
TOTAL INOPERATIVE TIME.....: 0  
TOTAL GCT EARNED AND PROJECTED...: 898  
TOTAL GCT EARNED.....: 898  
STATUTORY RELEASE DATE PROJECTED: 09-17-2005  
SIX MONTH /10% DATE.....: N/A  
EXPIRATION FULL TERM DATE.....: 03-03-2008

ACTUAL SATISFACTION DATE.....: 09-16-2005  
ACTUAL SATISFACTION METHOD.....: GCT REL  
ACTUAL SATISFACTION FACILITY....: CDT  
ACTUAL SATISFACTION KEYED BY....: BPC

DAYS REMAINING.....: 898  
FINAL PUBLIC LAW DAYS.....: 1

G0002 MORE PAGES TO FOLLOW . . .

NERH4	*	PUBLIC INFORMATION	*	10-21-2005
PAGE 005	*	INMATE DATA	*	08:36:05
		AS OF 04-06-1987		

REGNO.: 01215-039 NAME: SHAH, ROBERT ARBEB

RESP OF: CDT / GOOD CONDUCT TIME RELEASE

THE FOLLOWING SENTENCE DATA IS FOR THE INMATE'S PRIOR COMMITMENT.  
THE INMATE WAS SCHEDULED FOR RELEASE: 04-06-1987 VIA MAND REL

-----PRIOR JUDGMENT/WARRANT NO: 010 -----

COURT OF JURISDICTION.....: MICHIGAN, EASTERN DISTRICT  
DOCKET NUMBER.....: 81-80678  
JUDGE.....: GUY  
DATE SENTENCED/PROBATION IMPOSED: 04-08-1982  
DATE WARRANT ISSUED.....: N/A  
DATE WARRANT EXECUTED.....: N/A  
DATE COMMITTED.....: 05-24-1982  
HOW COMMITTED.....: US DISTRICT COURT COMMITMENT  
PROBATION IMPOSED.....: NO  
SPECIAL PAROLE TERM.....:

RESTITUTION...: PROPERTY: NO SERVICES: NO AMOUNT: \$00.00

-----PRIOR OBLIGATION NO: 010 -----

OFFENSE CODE....: 551  
OFF/CHG: UNARMED BANK ROBBERY T18:2113(A)

SENTENCE PROCEDURE.....: 4205(A) REG ADULT-ORIG TERM GRTR THAN 1YR  
SENTENCE IMPOSED/TIME TO SERVE.: 8 YEARS

-----PRIOR COMPUTATION NO: 010 -----

COMPUTATION 010 WAS LAST UPDATED ON 04-06-1987 AT MIL AUTOMATICALLY

THE FOLLOWING JUDGMENTS, WARRANTS AND OBLIGATIONS ARE INCLUDED IN  
PRIOR COMPUTATION 010: 010 010

G0002 MORE PAGES TO FOLLOW . . .

NERH4 \* PUBLIC INFORMATION \* 10-21-2005  
PAGE 006 OF 006 \* INMATE DATA \* 08:36:05  
AS OF 04-06-1987

REGNO.: 01215-039 NAME: SHAH, ROBERT ARBEB

RESP OF: CDT / GOOD CONDUCT TIME RELEASE  
PHONE...: 313-226-6186 FAX: 313-226-7327  
DATE COMPUTATION BEGAN.....: 04-08-1982  
TOTAL TERM IN EFFECT.....: 8 YEARS  
TOTAL TERM IN EFFECT CONVERTED...: 8 YEARS

JAIL CREDIT.....:	FROM DATE	THRU DATE
	01-03-1982	04-07-1982

TOTAL JAIL CREDIT TIME.....	95
TOTAL INOPERATIVE TIME.....	0
STATUTORY GOOD TIME RATE.....	8
TOTAL SGT POSSIBLE.....	768
PAROLE ELIGIBILITY.....	09-03-1984
STATUTORY RELEASE DATE.....	11-26-1987
TWO THIRDS DATE.....	05-04-1987
180 DAY DATE.....	07-06-1989
EXPIRATION FULL TERM DATE.....	01-02-1990

NEXT PAROLE HEARING DATE.....: N/A  
TYPE OF HEARING.....: CONTINUE TO EXPIRATION

ACTUAL SATISFACTION DATE.....: 04-06-1987  
ACTUAL SATISFACTION METHOD.....: MAND REL  
ACTUAL SATISFACTION FACILITY.....: MIL  
ACTUAL SATISFACTION KEYED BY.....: TZ

DAYS REMAINING.....: 1002  
FINAL PUBLIC LAW DAYS.....: 0

S0039 ALL CURRENT COMPS ARE SATISFIED

## **Document 1b**

WARDEN'S OFFICE

Type or use ball-point pen. If attachments are needed, submit four copies. Additional instructions on reverse.

From: Shawn Robert 04 JUL -9 PM 1:57 215-057 D.B MC Kean  
LAST NAME, FIRST, MIDDLE INITIAL REG. NO. UNIT INSTITUTION

Part A- INMATE REQUEST  
My. Dr. [illegible] response was a representation made without regard to study or studies made concerning deleterious side-effects of Seropack and also, no reference was made as to the effect over-dosage would have on my body. Dr. [illegible] continues to treat my legitimate medical concerns indifferently and makes no effort to take cognizance of symptoms manifested to him. He should be aware of the substantial risk to my health the Seropack regimen as prescribed, has created. His disregard and indifference exacerbates the problem.

7-9-04

DATE

[Signature]  
SIGNATURE OF REQUESTER

Part B- RESPONSE

DATE

WARDEN OR REGIONAL DIRECTOR

If dissatisfied with this response, you may appeal to the Regional Director. Your appeal must be received in the Regional Office within 20 calendar days of the date of this response.

ORIGINAL: RETURN TO INMATE

CASE NUMBER: 343051

CASE NUMBER: \_\_\_\_\_

Part C- RECEIPT

Return to:

LAST NAME, FIRST, MIDDLE INITIAL

REG. NO.

UNIT

INSTITUTION

SUBJECT: \_\_\_\_\_

DATE

RECIPIENT'S SIGNATURE (STAFF MEMBER)



SHAH, Robert Arbeb  
Reg. No.: 01215-039  
MCK 343051-F1

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**PART B - RESPONSE**

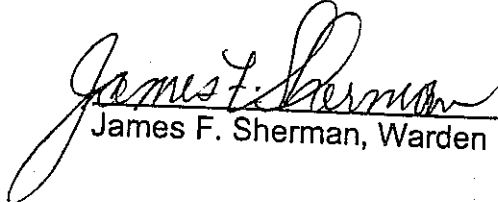
This is in response to your Request for Administrative Remedy received in my office on July 9, 2004, in which you claim indifference by a medical staff member for side effects caused by medication issued by the health services department.

Please refer to your response for your Request for Administrative Remedy, MCK 291765-F1, which addressed these same issues.

This is for informational purposes only.

In the event that you are not satisfied with this response, you may appeal within twenty (20) calendar days from the date of this response by submitting a BP-DIR-230 to the regional director.

7/29/04  
Date

  
James F. Sherman, Warden

NAME: SHAH, Robert  
Reg. No. 01215-039  
MCK 291765-F1

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**PART B-RESPONSE**

This is in response to your Request for Administrative Remedy receipted in my office on February 28, 2003, in which you claim your medication was changed by the Clinical Director causing severe side effects.

An investigation of your complaint reveals when you arrived at FCI McKean July 19, 2002 you were taking the following medication:

Klonopin 1.0 mg take one half tablet every day  
Venlafaxine 150 mg take one tablet every night  
Trazodone 100 mg take three tablets every night  
Quetiapine 200 mg take one tablet three times per day

You were continued on the same medication regiment that you arrived on. On August 2, 2002, you were evaluated by the psychiatrist per telemedicine. The psychiatrist recommended that the Klonopin be discontinued and the Quetiapine be increased to 300 mg three times per day. You were evaluated again by the psychiatrist October 25, 2002, and the Quetiapine dosing schedule was changed to 200 mg twice per day and 500 mg at night. The daily total dosage remained the same. On November 27, 2002, the quetiapine was decreased to 500 mg each night and lansoprazole was added for stomach discomfort. On December 2, 2002, the Quetiapine was discontinued and Klonopin was ordered 1 mg one tablet two times per day. On December 10, 2002, you reported to the medical officer you felt back to normal and requested to go back to work which was granted. On December 13, 2002, per telemedicine the Klonopin was discontinued. A telemedicine evaluation December 20, 2002, recommended to continue the Trazodone and discontinue the Venlafaxine. The last telemedicine evaluation was February 28, 2003, and recommended the current medication regiment be continued. You are currently on Trazodone 100 mg three tablets every day.

The psychiatrist has made some changes in your regiment according to your response to the medication and possible side effects. You will continue to be followed on a regular basis at clinic.

Based on this information, your Request for Administrative Remedy has been denied.

In the event that you are not satisfied with this response, you may appeal within twenty (20) calendar days from the date of this response by submitting a BP- DIR-230 to the regional director.

---

*"Sensitive-Limited Official Use Only"*

---

Date

John J. LaManna, Warden

*"Sensitive-Limited Official Use Only"*

## **Document 1c**

Type or use ball-point pen. If attachments are needed, submit four copies. One copy of the completed BP-DIR-9 including any attachments must be submitted with this appeal.

From: SHAH, ROBERT 01215-039 DB MCKEAN  
LAST NAME, FIRST, MIDDLE INITIAL REG. NO. UNIT INSTITUTION

Part A—REASON FOR APPEAL

ADMINISTRATIVE REMEDY AGAINST MR. MONTGOMERY-ASSISTANT HOSPITAL ADMINISTRATOR

Montgomery response was a representation made without regard to a study or studies made concerning deleterious side-effect of SEROQUEL and also no reference was made as to the effect of over-dosage would have on my body. Mr. Montgomery continue to treat my legitimate medical concerns indifferently, and made no effort to take cognizance of the symptoms manifested to him. He should be aware of the substantial risk to my health the SEROQUEL regimen, as perscribed, has created. His disregard and indifference exacerbrates the problem.

8-9-04  
DATE

Robert Shah  
SIGNATURE OF REQUESTER

Part B—RESPONSE

DATE

REGIONAL DIRECTOR

If dissatisfied with this response, you may appeal to the General Counsel. Your appeal must be received in the General Counsel's Office within 30 calendar days of the date of this response.

FIRST COPY: REGIONAL FILE COPY

CASE NUMBER: 343051-R1

Part C—RECEIPT

CASE NUMBER: \_\_\_\_\_

Return to: \_\_\_\_\_  
LAST NAME, FIRST, MIDDLE INITIAL REG. NO. UNIT INSTITUTION

SUBJECT: \_\_\_\_\_

**SHAH, Robert**

Reg. No. 01215-039

Appeal No. 343051-R1

Page One

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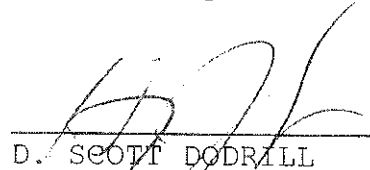
**Part B - Response**

In your appeal, you allege the Assistant Health Services Administrator (AHSA) at FCI McKean has disregarded studies conducted concerning the side effects of Seroquel and the effects of over dosage. You also claim he is indifferent to your legitimate medical concerns and state he should be aware of the substantial risk to your health that the Seroquel, as prescribed, has created.

A review of your appeal reveals that your complaint regarding the dosage of Seroquel that you were given by the Chief Psychiatrist at FMC Devens has been addressed in Request for Administrative Remedy No. 291765-F1. Additionally, your medical records reveal that you arrived at FCI McKean on July 19, 2002, with a history of post-traumatic stress disorder, major depression with psychotic features, poly-substance dependence, adult antisocial behavior to rule out borderline personality disorder, hypertension, chronic obstructive pulmonary disease, positive PPD and a benign lung nodule. You signed a consent form to use atypical anti-psychotic medication, Seroquel, a form which described common side effects. On May 26, 2004, you were in a meeting that included a staff physician, an Associate Warden and the AHSA. You explained to them your concern about your medications, the symptoms you have and what you feel were side effects. Your Post Traumatic Stress Disorder symptoms (PTSD) related to this were reviewed, as well as, related treatment. You may access routine sick call and have your concerns regarding medication side effects addressed. Medical staff advise that you are receiving appropriate medical care. Accordingly, your appeal is denied.

If you are dissatisfied with this response, you may appeal to the General Counsel, Federal Bureau of Prisons. Your appeal must be received in the Administration Remedy Section, Office of General Counsel, Federal Bureau of Prisons, 320 First Street, N.W., Washington, D.C. 20534, within 30 calendar days of the date of this response.

Date: September 15, 2004

  
D. SCOTT DODRILL  
Regional Director

## **Document 1d**

U.S. Department of Justice

## Central Office Administrative Remedy Appeal

Federal Bureau of Prisons

Type or use ball-point pen. If attachments are needed, submit four copies. One copy each of the completed BP-DIR-9 and BP-DIR-10, including any attachments must be submitted with this appeal.

From: SHAN, Robert 61215-039 03 FOI MONTGOMERY  
 LAST NAME, FIRST, MIDDLE INITIAL REG. NO. UNIT INSTITUTION

## Part A—REASON FOR APPEAL

The Response from the Regional Director ignores or mis-interprets two important points. Although it is true that I signed a "consent" form to receive Seroquel, the form provided was a pre-printed form used for myriad psychotropic medications, not specifically Seroquel. At the time, I was simply told to sign the form. No further advice or information was provided. Side effects were not discussed. I was not told that the dosage was far beyond that recommended by the manufacturer or approved by the FDA. The Response also ignores the fact that the over-medication created new medical problems and exacerbated existing problems. I have continuously sought diagnosis of the new problems and treatment for existing problems, but my complaints have been ignored and I have not had any staff person listen to my complaint regarding the problem with the over-medication. My courteous requests to Mr. Montgomery have been rudely and summarily dismissed. No one has taken the time to explain to me what further problems I might anticipate because of the over-medication. I have attached literature from both the drug manufacturer and the FDA in support.

7/24/05 DATE

Robert Shan SIGNATURE OF REQUESTER

## Part B—RESPONSE

DATE

GENERAL COUNSEL

SECOND COPY: REGIONAL FILE COPY

CASE NUMBER: 343051-A1

## Part C—RECEIPT

CASE NUMBER: 343051-A1

Return to: LAST NAME, FIRST, MIDDLE INITIAL REG. NO. UNIT INSTITUTION

SUBJECT: \_\_\_\_\_

DATE

SIGNATURE OF RECIPIENT OF CENTRAL OFFICE APPEAL

You contend you were told to sign a consent for the medication Seroquel, and that side effects were not explained. You also state that your dosage was far beyond the manufacturer's recommendation and FDA-approved maximum dose. You allege your previous Seroquel dose has created new symptoms.

Relevant portions of your medical record have been reviewed and reveal that the consent form signed allowing Seroquel to be prescribed contained proper information regarding common side effects of atypical antipsychotic medications, including Seroquel. Your signature on the consent form also serves to certify that its contents were understood, that you had no additional questions, and that you understood that you could stop taking the medication at any time by contacting the physician. Constipation is indicated as a possible side effect on the signed consent and was experienced as noted in your medical record. It is your responsibility to ensure that you understand forms to which you attach your signature, as it was you who signed the consent form.

FDA registration trials of antipsychotic agents do not address the effects of treatment on various illness phases. The trials also commonly exclude treatment-resistant patients and those with refractory illness. In these patients, for example, empirical trials of higher antipsychotic dosages is often considered as a clinical option. In your case, the maximum daily dose prescribed was 900mg in lieu of the manufacturer's recommended daily dose of 800 mg. Trials of Seroquel 1,000 mg to 1,400 mg per day have been studied with no significant changes observed regarding mean weight, glucose, total cholesterol, prolactin, or electrocardiogram Q-T wave intervals.

Your latest prescription of Seroquel was discontinued on December 2, 2002, and should be causing no further adverse effects. Descriptions of new symptoms you allegedly experience are not specified in your appeal. However, your medical record reflects that you have been evaluated and treated on numerous occasions for various ailments. You are therefore encouraged to continue to work with medical staff should you experience significant changes in your health.

Inasmuch as you request no specific relief, this response is for informational purposes only.

November 16, 2007  
Date

Harrell Watts  
Harrell Watts, Administrator  
National Inmate Appeals

## **Document 1e**

## High-dose antipsychotics: Desperation or data-driven?

*For patients on the brink of the neuroleptic threshold, risks of high-dose antipsychotics may outweigh any benefit.*

**Joseph M. Pierre, MD**

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Geffen School of Medicine at UCLA

Staff psychiatrist

VA West Los Angeles Healthcare Center

**Donna A. Wirshing, MD**

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Co-chief, Schizophrenia Treatment Unit

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Professor of clinical psychiatry

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Co-chief, Schizophrenia Treatment Unit

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When nothing else works, desperate clinicians are resorting to progressively more-tenuous and unpredictable treatments, trying to improve the lives of patients with refractory schizophrenia. High-dose antipsychotics is a common strategy.

Does boosting antipsychotic doses beyond the recommended range—but short of the neuroleptic threshold—enhance efficacy? This article attempts to answer that question by presenting the evidence on higher-than-recommended doses of atypical antipsychotics.

### Lessons from neuroleptics

Up to 30% of patients with schizophrenia do not respond to antipsychotics and are considered "treatment refractory."<sup>1</sup> Even among those who do respond, improving symptoms by 20%—as research defines "treatment response"—does not necessarily yield clinical or functional improvement. Clozapine is the only atypical antipsychotic with well-established efficacy in these chronically ill patients,<sup>2</sup> but its daunting side effects greatly curtail its use.

Before atypical antipsychotics, patients who did not respond to usual dosages of the typical neuroleptics were treated with higher dosages or switched to another drug class. Although many clinicians embraced high-dose neuroleptics, subsequent research discredited "rapid neuroleptization" in any clinical circumstance and showed that exceeding an antipsychotic's neuroleptic threshold—the dose at which extrapyramidal side effects (EPS) occur—reduces its efficacy (Figure 1).<sup>3-5</sup> In some instances, reducing neuroleptic dosages improves treatment-resistant patients' symptoms and reduces drug-induced side effects.<sup>6</sup>

Atypical antipsychotics are defined by their relative lack of EPS at recommended dosages (Figure 2). Because these agents can cause EPS if dosed too high, however, our

## Recovery from schizophrenia: Fact or fiction?

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historical habit of testing this dose limit risks losing "atypicality" and encountering other untoward events (Figure 3).

What is the safest, most effective dosage? Consider the evidence for each atypical antipsychotic.

**Risperidone**

**Recommended dosage too high?** When using atypicals at recommended doses, you are most likely to encounter the neuroleptic threshold with risperidone, with EPS risk increasing substantially at >6 mg/d.<sup>7</sup> Post-approval studies set the most effective and safest dosage at approximately 4 mg/d, though this dosage was not studied in North American pre-approval trials. Dosages of 2 to 4 mg/d have been associated with more-favorable outcomes, suggesting that the initial recommendation to titrate to 6 mg/d within the first 3 days was ill-advised.<sup>8</sup>

In our study of patients with treatment-refractory schizophrenia,<sup>9</sup> those treated with risperidone, 6 mg/d, improved significantly more after 4 weeks than did those receiving haloperidol, 15 mg/d, based on Brief Psychiatric Rating Scale (BPRS) scores. No additional benefit was seen after risperidone was increased to >6 mg/d at 8 weeks. Akathisia and tardive dyskinesia occurred significantly more often in the haloperidol group.

**Conclusion.** Some patients respond to higher-dose risperidone, but emerging EPS suggest the need to reduce the dosage rather than add an antiparkinsonian agent.

**Olanzapine**

**Mixed results.** Case reports suggest that some patients who did not respond to previous antipsychotic trials or olanzapine, 20 mg/d, improved significantly—without substantial side effects—when olanzapine was increased up to 60 mg/d.<sup>10-14</sup> Other case studies, however, report EPS, increased heart rate, increased transaminases, hyperprolactinemia, and prolonged QTc interval with high-dose olanzapine.<sup>14-16</sup>

In an open-label trial,<sup>17</sup> 43 patients with schizophrenia received olanzapine, up to 40 mg/d, after inadequate response to neuroleptics and risperidone or clozapine. Olanzapine was titrated to 20 mg/d by week 4 and increased 5 mg every 2 weeks if symptoms did not improve. After 14 weeks, improvement was modest and only 17% of patients met response criteria. However, >20 mg/d reduced symptoms more than did <20 mg/d, suggesting that high-dose olanzapine was more effective.

In a randomized trial,<sup>18</sup> patients who did not respond to at least one atypical antipsychotic then received 8 weeks of fixed, standard-dose treatment with (mean dosages):

- haloperidol, 18.9 mg/d
- risperidone, 7.9 mg/d
- olanzapine, 19.6 mg/d
- clozapine, 401.6 mg/d.

Flexible dosing was then allowed for 6 weeks, and mean dosages were:

- haloperidol, 25.7 mg/d
- risperidone, 11.6 mg/d
- olanzapine, 30.4 mg/d
- clozapine, 526.6 mg/d.

Symptoms improved modestly at best for all medications, although patients taking olanzapine or clozapine improved significantly more than those treated with haloperidol as shown by mean changes in total Positive and Negative Syndrome Scale (PANSS) scores.

**Recovery from schizophrenia: Fact or fiction?**

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PANSS scores for olanzapine-treated patients showed additional improvement at week 14—when higher dosages were used—compared with week 8. This was not the case for the other medications, for which response plateaued. These findings suggest that high-dose risperidone and haloperidol are incrementally ineffective, but high-dose olanzapine could help some patients with refractory symptoms.

Results were different in a randomized, double-blind, 16-week, crossover study,<sup>19</sup> when 13 patients with inadequate response to neuroleptics, risperidone, or conventional-dose olanzapine then received olanzapine, 50 mg/d, or clozapine, 450 mg/d. No olanzapine-treated patients and 20% of clozapine-treated patients met criteria for treatment response (20% improvement in BPRS score and final BPRS score <35 or 1-point improvement on Clinical Global Impressions-Severity of Illness scale).

Subjects switching from clozapine to olanzapine tended to worsen, whereas those switching from olanzapine to clozapine tended to improve. Olanzapine-treated patients experienced more anticholinergic side effects and more weight gain than did clozapine-treated subjects.<sup>20</sup>

**Conclusion.** These mixed findings on high-dose olanzapine suggest questionable efficacy in patients with treatment-resistant schizophrenia and an uncertain risk of increased toxicity.

**Quetiapine**

Early placebo-controlled studies of quetiapine in schizophrenia concluded that statistically significant improvement begins at 150 mg/d and falls off after 600 mg/d.<sup>21</sup> Although few high-dose quetiapine cases have been presented, clinical opinion holds that:

- most patients with chronic schizophrenia require 400 to 800 mg/d
- some treatment-refractory patients might benefit from >800 mg/d.

One patient responded to quetiapine, 1,600 mg/d, after not responding to olanzapine, 40 mg/d, and quetiapine, 800 mg/d. Constipation was the only reported side effect.<sup>22</sup>

Our group<sup>23</sup> reported a series of 7 patients who responded (by clinician report) to quetiapine, 1,200 to 2,400 mg/d, after not responding to quetiapine, 800 mg/d, or to neuroleptics, risperidone, or olanzapine. Six responded to high-dose quetiapine and 1 to high-dose quetiapine plus risperidone, 2 mg/d; 4 received adjunctive divalproex sodium, 1,500 to 3,000 mg/d. Psychopathology, violence, and behavioral disturbances were reduced throughout 5 to 14 months of monitoring. Side effects included sedation, orthostasis, and dysphagia.

When Nelson et al<sup>24</sup> treated 13 subjects for 14 weeks with quetiapine, 1,000 to 1,400 mg/d, mean weight, glucose, total cholesterol, prolactin, and QTc interval duration did not change significantly. Heart rate increased significantly (though not to tachycardia), and headache, constipation, and lethargy were the most frequent side effects.

**Summary.** Although encouraging, these reports are preliminary, unpublished, and lack peer review. Controlled trials of high-dose quetiapine's efficacy and safety are needed.

**Ziprasidone and aripiprazole**

No studies of high-dose ziprasidone or aripiprazole have been published. In premarketing trials:

- ziprasidone was studied at 200 mg/d and released with a maximum recommended dosage of 160 mg/d
- aripiprazole, 30 mg/d, was not more effective than 15 mg/d.<sup>25</sup>

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Deutschman et al<sup>26</sup> reviewed the charts of 31 patients who received ziprasidone, 240 to 320 mg/d, after an "incomplete" response to 160 mg/d. At the higher dosing:

- psychosis, affective symptoms, or anxiety improved in nearly one-half of patients
- 15% reported sedation, but most reported no side effects
- none developed QTc intervals >500 msec.

**Caveats and precautions**

These uncontrolled case reports and open-label studies do not "prove" efficacy or safety but reflect clinical practice. More than anything, they show that we need controlled trials to gauge high-dose antipsychotic therapy's efficacy and safety and to curb our collective habit of relying on anecdotal experience and idiosyncratic beliefs.

Despite its side-effect profile, clozapine remains the treatment of choice for refractory schizophrenia. Given high-dose antipsychotic therapy's uncertain efficacy and unknown risks, the evidence supports a clozapine trial before higher-than-recommended dosing is attempted.

Because educated guesswork plays a role in premarketing dosing studies, a medication's optimal dose may be:

- overestimated (as with risperidone)
- underestimated (as perhaps with olanzapine and quetiapine).

Keep in mind some important caveats when you consider giving a patient high-dose antipsychotic therapy (Box).<sup>27</sup> Of course, nonadherence is often the cause of apparent medication nonresponse. Increasing the dosage of a medication a patient is not taking rarely improves adherence. Interventions to enhance adherence—careful assessment, psychoeducation, and using long-acting intramuscular medication—may be useful.

For more information on this topic, [click here](#).

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**Related resources**

Marder SR, Essock SM, Miller AL, et al. The Mount Sinai Conference on the pharmacotherapy of schizophrenia. *Schizophrenia Bull* 2002;28:5-16.

Practice guideline for the treatment of patients with schizophrenia (2nd ed). *Am J Psychiatry* 2004;161(suppl):1-56.

Texas Medication Algorithm Project antipsychotic algorithm.

<http://www.mhmr.state.tx.us/centraloffice/medicaldirector/timascz1algo.pdf>

**Drug brand names**

[http://www.currentpsychiatry.com/2004\\_08/0804\\_Pierre.asp](http://www.currentpsychiatry.com/2004_08/0804_Pierre.asp)

11/9/2004

## **Document 1f**

UNITED STATES GOVERNMENT

# Memorandum

Northeast Regional Office, Philadelphia, PA  
FEDERAL BUREAU OF PRISONS

DATE: November 20, 2003

REPLY TO

ATTN OF: Henry J. Sadowski, Regional Counsel

SUBJECT: Administrative Tort Claim No. TRT-NER-2003-03388

TO: Robert Arbeb Shah, Reg. No. 01215-039  
FCI McKean

Your Administrative Tort Claim No. TRT-NER-2003-03388, dated June 23, 2003, and properly received in this office on June 30, 2003, has been considered for settlement as provided by the Federal Tort Claims Act (FTCA), 28 U.S.C. § 2672, under authority delegated to me by 28 C.F.R. § 543.30. You seek compensatory damages in the amount of \$5,000,000.00 for an alleged personal injury. Specifically, you claim medical staff at the Federal Correctional Institution (FCI), McKean, Pennsylvania, improperly prescribed you an antipsychotic medication, causing you severe mental deterioration, hallucination, abdominal pain, constipation, back pain, neck pain and dry mouth.

After careful review of this claim, I have decided not to offer a settlement. Investigation reveals you have a history of post-traumatic stress disorder, major depression with psychotic features, polysubstance dependence, adult antisocial behavior, hypertension, chronic obstructive pulmonary disease, positive ppd test and benign lung nodule. The medication you claim caused you injury, Seroquel, was part of your treatment regiment upon your arrival at FCI McKean. You were advised of the possible side effects and signed the treatment consent form. The medical record indicates you were appropriately prescribed this medication for the symptoms you present. It also indicates that long-term continued use has been appropriately prescribed in your case. You fail to show you have actually experienced a personal injury as the result of negligence on the part of any Bureau of Prisons' employee.

Accordingly, your claim is denied. If you are dissatisfied with this decision, you may seek reconsideration from this office or bring an action against the United States in an appropriate United States District Court within six (6) months of the date of this memorandum.

cc: John J. LaManna, Warden, FCI McKean

ACKNOWLEDGMENT OF RECEIPT

DENIAL OF TORT CLAIM

I, Robert Arbeb Shah, Reg. No. 01215-039, hereby acknowledge receipt this 25<sup>TH</sup> day of NOVEMBER, 2003, of the November 20, 2003, memorandum from Henry J. Sadowski, Regional Counsel, Northeast Region, Federal Bureau of Prisons, informing me of the denial of my tort claim (TRT-NER-2003-03388).

Robert Arbeb Shah  
Signature

Witnessed this 25<sup>TH</sup> day of NOVEMBER, 2003.

[Signature]  
Staff Witness

**FAX SERVICE**  
# PAGES 1 DATE 11/25/03 FAX #  
TO NEKO Legal  
FROM McKern Legal  
CO.  
PH # FAX #